UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Review of Protocol Modifications for "Sani-Cloth Germicidal Wipes"
EPA Reg. No. 9480-7
DP Barcode: D289589
Case No. 065184

From: Lorilyn M. Montford LM
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Applicant: Delta Analytical Corporation
7910 Woodmont Avenue
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Formulation:

Active Ingredient(s)	% by wt
n-alkyl(C_{12}67%, C_{14}25%, C_{16}7%, C_8, C_{10}, C_{18}, 1%) dimethyl benzyl ammonium chlorides	0.0175%
Isopropyl Alcohol	5.4800%
Inert Ingredients	94.5025%
Total	100.0000%

I. BACKGROUND

The product, Sani-Wipe (EPA Reg. No. 9480-7), is an EPA-approved food contact surface sanitizer for use on hard, non-porous surfaces. In a previous submission, the applicant requested an amendment to the registration of this product to add claims for use of the product as a sanitizing wipe on hard, non-porous, food contact surfaces in food service settings, restaurants, food processing areas, and households. This data submission is part of the requested final reports that the applicant is to submit in support of the stated amendment. The studies were conducted at Mycoscience Labs, Inc. located at 25 Village Hill Road in Willington, Connecticut 06279.

This data package contained two studies (MRID Nos. 458969-01 and 458969-02), *Statements of No Confidentiality Claims for both studies, and the last accepted label (dated July* 3, 2002).

II. USE DIRECTIONS

The product is designed to be used for sanitizing hard, non-porous, food-contact surfaces such as countertops, drain boards, and non-wood cutting boards. Directions on the last accepted label (dated July 3, 2002) provided the following information regarding preparation and use of the product as a food-contact surface sanitizer: Pre-clean if surface is visibly soiled. Wipe surface so that it remains visibly wet for 30 seconds. Let air dry.

The directions also provided the following instructions: Do not use to sanitize eating utensils, glassware, cookware, and food processing equipment. Do not apply directly to any type of human food. Do not use for cleaning or sanitizing human skin. Do not use as a diaper wipe or for personal cleansing.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Non-Residual Sanitization of Hard Inanimate Food-Contact Surfaces Using Pre-Saturated, Single Use Towelettes

Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in sanitizing hard surfaces. The standard test methods available (e.g., AOAC Germicidal Spray Products Test, AOAC Germicidal and Detergent Sanitizing Action Method), if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the AOAC Germicidal Spray Products Test against *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11299) on two carrier surfaces: (1) stainless steel or glass, and (2) plastic with a rough surface (i.e., plastic cutting

board). Inoculated carriers should be dried for 40 minutes at 30-37°C. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a 30-second holding time. Liquid expressed from the used towelette should also be subcultured. Tests are to be conducted in triplicate. Three product samples, representing three different batches, one of which is at least 60 days old, must be tested. Starting inocula must provide 75-125 x 10^6 CFU/mL on the parallel control surface. Additional organisms may be tested, using two batches of product. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. Subcultures of the liquid expressed from the used towelettes should be negative for growth. The study report must provide systematic and complete descriptions of the tests employed and the results obtained. Label directions must state that the towelette must be visibly wet (saturated) before use, and the treated surface must be visibly wet after use. Additionally, the label must identify the recommended maximum surface area to be treated, which must be reflective of the surface area tested in the study. The above Agency standards are presented in the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes. This guidance does not address products for use on utensils, glasses, food containers, dishes, and food processing equipment.

IV. COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 458969-01 "Nice-Pak Products, Inc. Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Non-Food Contact Surfaces,"by Richard E. Arsenault. Study conducted at Mycoscience Labs, Inc. Study completion date - March 25, 2003.

This study was conducted against *Salmonella choleraesuis* (ATCC 10708). Two lots (Lot Nos. 2J149 EUS and 2J097 EUS) of the product, Sani-Wipe, were tested. The product was tested as received, no preparation was necessary. Each textured high-density polyethylene (HDPE) surface was inoculated with 0.125 mL of the prepared culture suspension so that the total inoculum volume was 1.0 mL per eight 6" x 12" sections. The inoculum was spread uniformly over each surface section and dried at room temperature for 40 minutes prior to performing the testing. One wipe (8 x 10 in dimension) was used to wipe 4ft.^{2} of inoculated surface area (consisting of eight 6" x 12" sections). The wiped surfaces were allowed to sit for five minutes and then were transferred to a sterile stomacher bag containing 3,000 mL of sterial AOAC neutralizer solution. Five minutes after wiping the last surface, the wipe was transferred to 200 mL of sterile AOAC neutralizer blank solution. The (8) composited surfaces and wipe were then immediately sonicated for five minutes, followed by agitation by hand. Surface and wipe suspensions were assayed for surviving numbers of microorganisms using membrane filtration technique. Appropriate aliquots, such as 3 mL and 30 mL of the sample surface extracts and 2 mL and 20 mL of the wipe extracts were filtered through individual sterile bacterial retentive filters followed by a 50 mL rinse with AOAC neutralizing solution. The membrane

filters were transferred to the surface of Tryptone Glucose Extract Agar plates containing 25 mL of AOAC stock neutralizer/L. the plates were incubated at 35 - 37°C for a minimum of 48 hours and then were enumerated. Controls included parallel controls, neutralizer effectiveness, and confirmation of the challenge microorganism.

2. MRID 458969-02 "Nice-Pak Products, Inc. Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Non-Food Contact Surfaces," by Richard E. Arsenault Study conducted at Mycoscience Labs, Inc. Study completion date - March 25, 2003.

This study was conducted against *Salmonella choleraesuis* (ATCC 10708). Two lots (Lot Nos. 2J149, 2J097) of the product, Sani-Wipe, were tested. The product was tested as received, no preparation was necessary. Each glass surface section was inoculated with 0.125 mL of the prepared culture suspension so that the total inoculum volume was 1.0 mL per eight 6" x 12" sections. The inoculum was spread uniformly over each surface section, and dried at room temperature for 40 minutes prior to performing the testing. One wipe (8 x 10 in dimension) was used to wipe 4ft.^{2} of inoculated surface area (consisting of eight 6" x 12" sections). The wiped surfaces were allowed to sit for five minutes and were then transferred to a sterial stomacher bag containing 3,000 mL of sterile AOAC neutralizer solution. Five minutes after wiping the last surface, the wipe was transferred to 200 mL of sterile AOAC neutralizer blank solution. The eight (8) composited surfaces and wipe were then immediately sonicated for five minutes, followed by agitation by hand. Surface and wipe suspensions were assayed for surviving numbers of microorganisms using membrane filtration technique. Appropriate aliquots, such as 3 mL and 30 mL of the sample surface extracts and 2 mL and 20 mL of the wipe extracts were filtered through individual sterile bacterial retentive filters followed by a 50 mL rinse with AOAC neutralizling solution. The membrane filters were transferred to the surface of Tryptone Glucose Extract Agar plates containing 25 mL AOAC stock neutralizer/L. The plates were incubated at 35 - 37°C for a minimum of 48 hours and were then enumerated. Controls included parallel controls, neutralizer effectiveness, and confirmation of the challenge microorganism.

V. RESULTS

MRID Number: 458969-01
Test Organism: *Salmonella choleraesuis* on textured HDPE 4ft.^{2} Surface
Lot Number: 2J149 EUS

Replicate	Dilution Filtered	CFU/Filter	CFU Recovered	Total CFU Recovered	Reduction
1) Surface	1:100 (30mL)	0	$<1.0 \times 10^2$	$<1.1 \times 10^2$	.99.99%
1) Wipe	1:10 (20mL)	0	$<1.1 \times 10^1$		
2) Surface	1:100 (30mL)	0	$<1.1 \times 10^2$	$<1.1 \times 10^2$	99.99%
2) Wipe	1:10 (20mL)	0	$<1.0 \times 10^1$		
3) Surface	1:100 (30mL)	0	$<1.0 \times 10^2$	$<1.1 \times 10^2$	99.99%
3) Wipe	1:10 (20mL)	0	$<1.0 \times 10^1$		
Parallel Control Surface Wipe	 1:300,000 1:2,000,000	 193 95	 5.79×10^7 1.9×10^8	2.48×10^8	NA

MRID Number: 458969-01
Test Organism: *Salmonella choleraesuis* on textured HDPE 4ft.^{2} Surface
Lot Number: 2J097 EUS

Replicate	Dilution Filtered	CFU/Filter	CFU Recovered	Total CFU Recovered	Reduction
1) Surface	1:100 (30mL)	0	$<1.0 \times 10^2$	$<1.1 \times 10^2$	>99.99%
1) Wipe	1:10 (20mL)	0	$<1.0 \times 10^1$		
2) Surface	1:100 (30mL)	0	$<1.0 \times 10^2$	$<1.1 \times 10^2$	>99.99%
2) Wipe	1:10 (20mL)	0	$<1.0 \times 10^1$		
3) Surface	1:100 (30mL)	0	$<1.0 \times 10^2$	$<1.1 \times 10^2$	>99.99%
3) Wipe	1:10 (20mL)	0	$<1.0 \times 10^1$		
Parallel Control Surface Wipe	 1:300,000 1:2,000,000	 98 46	 2.94×10^7 9.2×10^7	1.21×10^8	NA

MRID Number: **458969-02**
Test Organism: ***Salmonella choleraesuis*** **on glass 4ft.^{2} Surface**
Lot Number: **2J149 EUS**

Replicate	Dilution Filtered	CFU/Filter	CFU Recovered	Total CFU Recovered	Reduction
1) Surface	1:100 (30mL)	0	$<1.0 \times 10^2$	$<1.1 \times 10^2$	>99.99%
1) Wipe	1:10 (20mL)	0	$<1.1 \times 10^1$		
2) Surface	1:100 (30mL)	0	$<1.1 \times 10^2$	$<1.1 \times 10^2$	>99.99%
2) Wipe	1:10 (20mL)	0	$<1.0 \times 10^1$		
3) Surface	1:100 (30mL)	0	$<1.0 \times 10^2$	$<1.1 \times 10^2$	>99.99%
3) Wipe	1:10 (20mL)	0	$<1.0 \times 10^1$		
Parallel Control Surface Wipe	 1:300,000 1:2,000,000	 50 47	 1.5×10^7 9.4×10^8	1.09×10^8	NA

MRID Number: **458969-02**
Test Organism: ***Salmonella choeraesuis*** **on glass 4ft.2 Surface**
Lot Number: **2J097**

Replicate	Dilution Filtered	CFU/Filter	CFU Recovered	Total CFU Recovered	Reduction
1) Surface	1:100 (30mL)	0	$<1.0 \times 10^2$	$<1.1 \times 10^2$	>99.99%
1) Wipe	1:10 (20mL)	0	$<1.0 \times 10^1$		
2) Surface	1:100 (30mL)	0	$<1.0 \times 10^2$	$<1.1 \times 10^2$	>99.99%
2) Wipe	1:10 (20mL)	0	$<1.0 \times 10^1$		
3) Surface	1:100 (30mL)	0	$<1.0 \times 10^2$	$<1.1 \times 10^2$	>99.99%
3) Wipe	1:10 (20mL)	0	$<1.0 \times 10^1$		
Parallel Control Surface Wipe	 1:300,000 1:2,000,000	 50 47	 1.17×10^7 1.64×10^8	1.76×10^8	NA

VI. CONCLUSIONS

1. The submitted efficacy data (MRID No.458969-01) does indeed support the use of the product, Sani-Wipe, as a non-food contact surface sanitizer when tested against *Salmonella choleraesuis* in the presence of a 5% organic soil load on 4ft.^{2} textured HDPE surfaces for a contact time of 5 minutes.

2. The submitted efficacy data (MRID No. 458969-02) does indeed support the use of the product, Sani-Wipe, as a non-food contact surface sanitizer when tested against *Salmonella choleraesuis* in the presence of a 5% organic soil load on 4ft.^{2} glass surfaces for a contact time of 5 minutes.

VII. RECOMMENDATIONS

1. The label claims (as supported by MRID Nos. 458969-01 and 456989-02) are acceptable regarding the use of the product, Sani-Wipe, as a non-food contact surface sanitizer against *Salmonella choleraesuis* in the presence of a 5% organic soil load on hard, non-porous surfaces for a contact time of 5 minutes.